

WHAT IS CLAIMED IS:

- 1 1. A method of controlling a penetrating member, the method
2 comprising:
3 (a) providing a device comprising a penetrating member driver having
4 a position sensor and a processor;
5 (b) accelerating the penetrating member towards a target tissue; and
6 (c) using a control algorithm to control the driver to move the
7 penetrating member to follow a desired velocity trajectory.
- 1 2. A method of body fluid sampling comprising: [2687]
2 moving a penetrating member at conforming to a selectable velocity
3 profile or motion waveform;
4 using a pie-shaped cartridge for housing said penetrating member;
5 piercing a storage area having a sensing area;
6 piercing another storage area having an enzyme area separate from the
7 sensing area prior to piercing;
8 causing fluid to first flow to the enzyme area and then to the sensing area.
- 1 3. The device of claim 1 further comprising storing said enzyme area
2 in an inert environment different from an environment for the sensing area.
- 1 4. A device for body fluid sampling usable with a cartridge housing a
2 plurality of penetrating members, the device comprising:
3 a housing;
4 a penetrating member driver coupled to said housing and for use with said
5 cartridge;
6 a processor for controlling said penetrating member driver to move at least
7 one of said penetrating members at velocities which conform with a selectable velocity
8 profile;
9 a storage area having a sensing area;

10 another storage area having an enzyme area separate from the sensing area
11 prior to piercing;

12 wherein said penetrating member pierces opens both storage areas upon
13 member actuation and causing body fluid to first flow to the enzyme area and then to the
14 sensing area.

1 5. A method of body fluid sampling comprising: [2599]
2 moving a penetrating member at conforming to a selectable velocity
3 profile or motion waveform;
4 achieving higher rates of spontaneous blood and higher spontaneous yields
5 by controlling depth of penetration.

1 6. The device of claim 1 wherein the penetrating member trajectory
2 waveform contains a stationary portion.

1 7. A device for body fluid sampling usable with a cartridge housing a
2 plurality of penetrating members, the device comprising:
3 a housing;
4 a penetrating member driver coupled to said housing and for use with said
5 cartridge;
6 a processor for controlling said penetrating member driver to move at least
7 one of said penetrating members at velocities which conform with a selectable velocity
8 profile.

1 8. The device of claim 3 comprising a window allowing a user to see
2 the cartridge while the cartridge is in said housing.

1 9. The device of claim 3 comprising display showing device status.

1 10. The device of claim 3 comprising display showing lancing
2 performance.

1 11. The device of claim 3 comprising display showing lancing
2 parameters.

1 12. The device of claim 3 comprising a single button for actuating said
2 penetrating member driver along an inbound path into tissue and then an outbound path
3 out of the tissue.

1 13. The device of claim 3 wherein said penetrating member driver
2 moves an active one of said penetrating members along a velocity profile that reduces
3 initial pain and residual pain to levels below that of known devices.

1 14. The device of claim 3 wherein said penetrating member driver
2 moves an active one of said penetrating members along a velocity profile that reduces
3 initial pain and residual pain to levels at least 1.5 times less than that of known devices.

1 15. The device of claim 3 wherein said penetrating member driver
2 moves an active one of said penetrating members along a velocity profile that reduces
3 residual pain to levels at least 2 times less than that of known devices.

1 16. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising: [2685]
3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;
5 a penetrating member coupler attached to said driver;
6 a cutting device that simultaneously cuts a sterility barrier on said cartridge
7 while moving along a path that rotates the cartridge about its center to align the newly
8 opened cavity in the cartridge with the penetrating member coupler.

1 17. The device of claim 1 wherein the penetrating member driver is
2 coupled to a position sensor, said sensor used to detect a position of the active one of said
3 penetrating member.

1 18. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:
3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;
5 a penetrating member coupler attached to said driver;

6 a cutting device that simultaneously cuts a sterility barrier on said cartridge
7 while moving along a path that rotates the cartridge about its center to align the newly
8 opened cavity in the cartridge with the penetrating member coupler;
9 a display coupled to the driver for showing the number of lancets
10 remaining.

1 19. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising: [2686]
3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;
5 a housing coupled to said driver;
6 a display on said housing showing a number of unused penetrating
7 members remaining.

1 20. The device of claim 1 wherein the penetrating member driver is
2 coupled to a position sensor, said sensor used to detect a position of the active one of said
3 penetrating member.

1 21. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:
3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;
5 a housing having a rectangular configuration.

1 22. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:
3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;
5 a housing having a golden color;
6 a position sensor, said sensor used to detect a position of the active one of
7 said penetrating member.

1 23. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:
3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a cavity to house the cartridge containing said penetrating members, said
6 cartridge being a circular disc having a fracturable sterility seal covering a top opening,
7 and a side opening.

1 24. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 electronic setting of lancing parameters used by said penetrating member
6 driver.

1 25. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 settings for lancing parameters used by said penetrating member driver
6 remain in memory without battery.

1 26. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a processor having a safety feature such that the penetrating member driver
6 only lances material with properties similar to skin.

1 27. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a processor having a safety feature such that the penetrating member driver
6 does not fire the active penetrating member in to air or materials harder than flesh.

1 28. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a processor having a safety feature such that the penetrating member driver
6 wherein a hard detect or an impact against material harder than tissue invalidates usage of
7 the penetrating member.

1 29. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a display showing penetrating members left/penetrating members spent.

1 30. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 depth setting of penetrating member penetration into tissue independent of
6 front end geometry.

1 31. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a processor programmed to track position and energy used by the driver to
6 sense position or proximity of skin.

1 32. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a display that has a screen saver.

1 33. A body fluid sampling device for use with a cartridge containing a
2 plurality of penetrating members comprising:

3 a penetrating member driver for moving an active one of said penetrating
4 members from a first position outward to penetrate tissue;

5 a display that relays a "too deep" signal to a user based on the lancing
6 event.

- 1 34. A fluid sampling device comprising:
2 a housing;
3 a cartridge defining a plurality of cavities; said cartridge sized to fit within
4 said housing; and
5 a plurality of penetrating members at least partially contained in said
6 cavities of the cartridge wherein the penetrating members are slidably movable to extend
7 outward from said cartridge to penetrate tissue, said cavities each having a longitudinal
8 opening providing access to an elongate portion of the penetrating member;
9 a sterility barrier coupled to said cartridge, said sterility barrier covering a
10 plurality of the longitudinal openings, wherein the sterility barrier covering the lateral
11 openings is configured to be moved so that the elongate portion may be accessed by the
12 gripper without touching the barrier; and
13 a slider located on a surface of said housing, said slider movable in a linear
14 direction to rotate said cartridge to bring an unused penetrating member into position for
15 use;
16 a tooth gear coupled to said slider to control a distance said slider can
17 travel;
18 a follower coupled to said slider;
19 a cam surface engaged by said follower to lift said cartridge a desired
20 distance above a first position to allow for rotation of the cartridge without engaging a
21 gripper used to advance the penetrating member.
- 1 35. The device of claim 1 wherein said cam surface is aligned parallel
2 to said slider.
- 1 36. The device of claim 1 wherein said linear motion of the cam rotates
2 the cartridge and moves a plunger to break the sterility barrier on the cartridge.
- 1 37. The device of claim 1 wherein cam surface comprise a linear strip
2 of material with at least two raised portions and two depressed portions.
- 1 38. A device for use in penetrating tissue to obtain a body fluid sample,
2 comprising:
3 a cartridge; and

4 a plurality of penetrating members slidably coupled to the cartridge, each
5 of said penetrating members having a distal end sufficiently sharp to pierce tissue and
6 each of said penetrating members being moveable relative to the other ones of the
7 penetrating members, so that the distal end of the respective penetrating member is
8 movable to penetrate tissue;
9 wherein each of said penetrating member is a bare lancet does not
10 penetrate an outer sterility barrier during actuation.

1 39. A device comprising:
2 a cartridge having a plurality of cavities; and
3 a plurality of penetrating members at least partially contained in said
4 cavities of the single cartridge wherein the penetrating members are slidably movable to
5 extend outward from lateral openings on said cartridge to penetrate tissue;
6 a sterility barrier coupled to said cartridge, said sterility barrier covering a
7 plurality of said lateral openings, wherein the sterility barrier covering the lateral
8 openings is configured to be moved so that a penetrating member exits the lateral opening
9 without contacting the barrier.

1 40. The device of claim 39 wherein the sterility barrier covering the
2 lateral openings is configured to be moved substantially vertically so that a penetrating
3 member exits the lateral opening without contacting the barrier.

1 41. A device comprising:
2 a housing;
3 a penetrating member driver;
4 a cartridge containing a plurality of penetrating members;
5 a display on said cartridge;
6 a linear slider on the housing, said slider coupled to a rod;
7 said rod moving with said slider, said rod having at least one roller
8 using the linear motion of the slider to rotate the cartridge, punch open a
9 new cavity and load a new penetrating member.

1 42. A method of indexing comprising:
2 moving a linear slider;
3 said linear slider coupled to a rod;

4 said rod moving with said slider, said rod having at least one roller
5 using the linear motion of the slider and linear motion of the rod to push at
6 least one linear slider and to roll a roller along a linear cam surfaces to lift clear a drive
7 assembly, rotate the cartridge, punch open a new cavity and load a new penetrating
8 member.